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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,005	06/28/2001	Hakuo Ikegami	IKEGAMI=2	6398

7590 10/22/2002
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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/22/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/893,005

Applicant(s)

IKEGAMI ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 31 July 2002, paper number 7.
2. Applicant has canceled claims 1-10, and added new claims 11-30. Claims 11-30 are pending. Claims 22-30 are nonelected. Claims 11-21 are examined in the instant action.
3. This action is made FINAL, necessitated by Applicants amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

6. Newly submitted claims 22-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions I (claims 11-21) and II (claims 22-30) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product; the transgenic plants can be used for molecular farming to produce and isolated the protein of interest.

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7. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112 second paragraph

8. Claims 11-21 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

In claim 11, "obtainable" should be replaced by "obtained", since no conditions are set forth for "obtainable". How is a "plant body" different from a "plant"? "In an amount effective" is unclear. Effective for what? Does this refer to an expression level, or to an amount of plant body taken orally? Diseases "susceptible to" is unclear. Is the protein the cause or the treatment of the disease? "also" should be inserted in front of "endogenously".

Claim 11 seems to place humans and mammals in different categories, however claim 12 is drawn to mammalian cytokines. Does this exclude human cytokines?

Does claim 14 mean that any mammalian source can be used to treat any mammalian disease? Human interferon is not equivalent to mouse interferon, for example.

In claim 15, "edible" plant is unclear because this necessarily refers to an organism for which the plant is an edible foodstuff. For instance, some plants are edible to cattle (ruminants) and not to human.

In claim 17, "added" is ambiguous. At what stage is the trehalose added? Does "added" mean transgenic?

In claims 20 and 21, what does "processed" mean? Applicant gives a list of processes, but does not state what is kept and what is discarded from any given step. For example, "extracting": if a plant is extracted by lyophilization, removing the water, and leaving the dehydrated plant material, the water removed is a product of the extraction. Is this Applicant's intent?

In claim 11, "physiologically active proteins" remains rejected, for reasons of record.

Applicant traverses primarily stating: that this term has been defined on page 3 bridging to page 4 of the specification. And that this is a commonly used term as evidenced by use of the term in the cited and applied Goodman patent US 4,956,282.

Applicant traversal has been considered and is unpersuasive, because the definition given by applicant does not specify what it is about "physiologically active proteins" that distinguishes them from other proteins. The use of the term by Goodman does not clarify the term in the instant case. Introducing definitions from another patent, and Applicant saying that definition is what he meant, is not persuasive because the Specification must be clear and concise, as enabled as of the time of filing. Goodman is not an authoritative text and does not provide the requisite definition to clarify this phrase.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 112, first

9. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "nerve growth factor, epidermal growth factor, platelet derived growth factor, transforming growth factor alpha, growth factor beta, growth hormone, insulin and steroids" are not supported by the specification.

Claim Rejections - 35 USC § 102

10. Claims 11-21 remain rejected under 35 USC 102 (b) as being anticipated by Goodman, et al (US #4, 956, 282, issued September 11, 1990), for reasons of record.

Applicant traverses, stating primarily: that Goodman teaches the use of plant cells as biological factories, whereas Applicant teaches the use of transgenic plants for oral administration.

Applicant traversal has been considered and is unpersuasive, because the intended use has no patentable weight in the claim. In response to applicant's arguments, the recitation of oral administration has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to

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stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant further traverses, stating primarily: particular levels of pharmacologically active proteins when produced in plants are more effective than the same pharmacologically active protein, isolated and used.

Applicant traversal has been considered and is unpersuasive, because the claims are not drawn to any particular level of expression. Applicant's arguing specific levels is not commensurate to the scope of the claims.

REMARKS

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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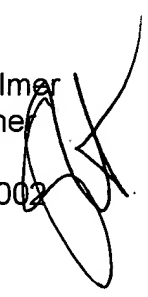
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer
Patent Examiner
Art Unit 1638
October 21, 2002




10/21/02
PHUONG T. BUI
PRIMARY EXAMINER